

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
AT CLARKSBURG**

ASTRAZENECA AB and ASTRAZENECA
PHARMACEUTICALS LP,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS INC. and
KINDEVA DRUG DELIVERY L.P.,

Defendants.

Civil Action No. 1:18-cv-00193-IMK-RWT

ASTRAZENECA AB and ASTRAZENECA
PHARMACEUTICALS LP,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS INC. and
KINDEVA DRUG DELIVERY L.P.,

Defendants.

Civil Action No. 1:19-cv-00203-IMK-RWT

**JOINT STATUS REPORT
REGARDING TRIAL SCHEDULE**

Pursuant to the Court’s oral order at the March 22, 2022 hearing, the parties submit the following status report regarding the upcoming trial on remand.

I. Scope of Trial

A. AstraZeneca’s Position

The parties have agreed in principle to limit the scope of trial to invalidity of U.S. Patent 10,166,247 (“the ’247 patent”) and are negotiating a stipulation to that effect. The parties, however, disagree as to whether Mylan is permitted to assert obviousness of the ’247 patent. AstraZeneca’s position is that law of the case precludes Mylan from relitigating the factual findings relating to the Court’s decision following the trial that Mylan had failed to prove obviousness, a judgment that was affirmed on appeal. Those findings, including for instance that the person of ordinary skill would not have been motivated to use HFA227—“a fatal choice,” *AstraZeneca AB v. Mylan Pharms. Inc.*, 552 F. Supp. 3d 200, 218 (N.D. W. Va. 2021)—cannot be relitigated as a matter of law and mandate judgment of nonobviousness as to the claims of the ’247 patent, all of which are directed to compositions comprising budesonide and formoterol formulated with HFA 227, PVP, and PEG. *See Ormco Corp. v. Align Tech.*, 498 F.3d 1307, 1319–20 (Fed. Cir. 2007) (law of the case bars relitigating obviousness of similar claims in related patent); *Smith Int’l v. Hughes Tool*, 759 F.2d 1572, 1576–78 (Fed. Cir. 1985). Dr. Pritchard previously opined in his expert report that the ’247 patent claims “recite limitations that are identical or obvious, minor variations of those recited” in the patents at issue at trial. Pritchard Opening Rep. ¶ 185.

B. Mylan’s Position

Mylan concurs that the parties have agreed in principle to limit the scope of the trial to

invalidity of the '247 patent and intend to file a stipulation to that effect.¹ Thus, the parties agree that trial will include Mylan's indefiniteness, written description, and enablement challenges to the asserted claims of the '247 patent.

Mylan has always and continues to maintain its defense that the '247 patent is invalid as obvious. AstraZeneca's position that law of the case bars Mylan's obviousness defense to the '247 patent claims is wrong. Mylan strenuously disagrees with AstraZeneca's inaccurate portrayal of the case law and its reliance on misleading excerpts from Dr. Pritchard's expert report. However, Mylan did not understand the court to invite the parties to brief substantive issues in this status report and, therefore, Mylan will defer its response until such time as AstraZeneca actually submits a motion on this issue to the Court.

II. Trial Dates

A. AstraZeneca's Position

AstraZeneca's consistent position has been to try this case as expeditiously as possible following the Federal Circuit's remand. During the March 22 conference, the Court confirmed that the earliest week it is available to hold trial was the week of April 18 and explained that week was its preference. AstraZeneca is prepared to proceed to trial that week, and AstraZeneca's expert Dr. Paul Young is available and can testify either in person or remotely. As explained during the conference, AstraZeneca believes that two days of trial would be sufficient and proposes that trial begin on April 21.

The parties have met and conferred three times since the March 22 conference. Thus far, Mylan has been unable to confirm or rule out Dr. Pritchard's availability to testify at trial on any

¹ The parties' stipulation moots Defendants' fully-briefed motion for partial summary judgment of no infringement under the doctrine of equivalents (ECF Nos. 245, 261, 275).

day of the week of April 18, or even clarify when Mylan would know of Dr. Pritchard's availability that week. Mylan also has not offered any days on which Dr. Pritchard would be available for a *de bene esse* deposition, which the Court suggested as a possibility in the event of Dr. Pritchard's unavailability. The parties accordingly have not been able to agree on the scheduling of trial. Mylan's delay prejudices the prompt resolution of this case and leaves the parties and the Court in limbo with only three weeks until the Court's (and AstraZeneca's) preferred week of trial.

Contrary to Mylan's position below, withdrawal of AstraZeneca's motion for preliminary injunction does not support delaying trial until June. AstraZeneca withdrew that motion in view of the Court's availability to try this case quickly in April and to avert the waste of the Court's and the parties' resources litigating back-to-back preliminary injunction and trial proceedings involving the same arguments regarding the same patents. Dkt. No. 528. There is no lack of "urgency"; should Mylan upset the status quo between now and trial, AstraZeneca intends to seek injunctive relief.

Mylan's latest proposal in the meet and confer process flips the presentation of evidence such that Dr. Young would be required to testify first (sometime during the week of April 18) as to the '247 patent's validity, an issue on which Mylan bears the burden of proof, and Dr. Pritchard would be allowed to testify second on April 26. Mylan's proposal is misguided. As an initial matter, AstraZeneca does not understand the Court to have suggested that it has availability on April 26. More importantly, as Mylan argued previously when AstraZeneca requested that an inventor testify first at the October 2020 trial, having the patentee "'go first with testimony on validity, thereby ignoring the rules applicable to all other types of litigation in which a statute or case law has assigned burdens of proof' has 'frequently resulted in cluttered records, irrelevant detours, undue burdens on the judicial process, and unnecessary work for the trial court.'" Dkt.

No. 345 at 12 (quoting *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1570–71 (Fed. Cir. 1986)); see Howard Markey, *On Simplifying Patent Trials*, 116 F.R.D. 369, 374–75 (1987) (“Trial time should not be wasted while a patentee attempts to disprove a defense that has not yet been presented.”). Mylan can provide no reason why its validity expert should go second in a trial only about validity, particularly given that AstraZeneca and Dr. Young should not be left to guess as to exactly what Dr. Pritchard’s testimony will be at trial. Mylan contends that this scenario is different from the order-of-presentation dispute between the parties before the first trial, which concerned when *fact* witnesses should testify. But here, the case for observing the ordinary sequence is far stronger: fact witnesses offer testimony based on their personal experience and observations; in contrast, Dr. Young will offer testimony *as an expert responding to Dr. Pritchard*. It is nonsensical for Dr. Young to respond to testimony that Dr. Pritchard has not yet offered.

Consequently, Mylan should offer dates for Dr. Pritchard to testify by *de bene esse* deposition. The video of his testimony would then be played at trial prior to Dr. Young’s. Mylan’s response to this alternative suggested by the Court is only a generic objection to *de bene esse* depositions, but Mylan offers no particular reason why this traditional way to obtain testimony from an unavailable witness (as Dr. Pritchard apparently is) is unsuitable here.

We thank the Court for its attention to this matter.

B. Mylan’s Position

Mylan intends to call Dr. Pritchard as its chief affirmative live witness on the invalidity of the ’247 patent. As previewed with the Court during last week’s hearing, Dr. Pritchard will be on a long-scheduled trip during the week following Easter that was very difficult to arrange. As of now, Mylan has been unable to reliably secure a work-around—especially one which would permit Dr. Pritchard to testify, observe the testimony of AstraZeneca’s Dr. Young, and subsequently

provide rebuttal testimony. With apologies to the Court for any inconvenience, given the importance of Dr. Pritchard to Mylan's case, we believe that the best option to accommodate AstraZeneca's desire to proceed in April is described below.

Mylan has proposed alternate solutions to AstraZeneca, but each has been rejected. *First*, Mylan offered to do short openings and the direct and cross examination of AstraZeneca's Dr. Young the week of April 18, and to conduct Dr. Pritchard's direct and cross examination on April 26—a date that is two business days after that which was offered by the Court and that Mylan understands may be open on the Court's calendar. AstraZeneca rejects that proposal because it takes the witnesses out of order. That is true, but it is counterbalanced by two other factors. First, Mylan would be prejudiced if it is unable to obtain the testimony of its key witness or have truncated access to him preventing consultation on responses to arguments made by AstraZeneca's expert. Second, as the party with the burden of proof, Mylan is entitled to recall Dr. Pritchard for a reply case and have the last word on invalidity. As the article authored by Judge Markey cited by AstraZeneca recognizes, "patentee's lawyers have no more right to deprive defendants of their right to have the last word on their invalidity defense than defendants have to deprive patentees of their right to have the last word on infringement." Howard Markey, *On Simplifying Patent Trials*, 116 F.R.D. 369, 374 (1987). As Mylan informed AstraZeneca, under Mylan's proposal there would be no need to recall Dr. Pritchard a second time and he would testify only once, thus streamlining proceedings. AstraZeneca attempts to draw a distinction between fact and expert witnesses, claiming it is "nonsensical" for expert witnesses to testify out of order. But, unlike fact witnesses, AstraZeneca has multiple depositions and expert reports from Dr. Pritchard.

AstraZeneca's reference to the parties' positions with respect to the order of witnesses at the October 2020 trial misses the mark. The issue there was AstraZeneca's desire to call its two

inventors as the first two witnesses in *Mylan's* case-in-chief. AstraZeneca contended this would “facilitate the presentation of evidence.” Dkt. No. 345 at 10. That is not the issue here. Given the parties’ agreement to narrow the case, it appears likely that the *only* two witnesses testifying at trial will be Dr. Pritchard and Dr. Young. The order in which they testify will create no confusion as to the presentation of evidence or impose any undue burdens on the Court. Rather, Mylan’s proposal will solve a genuine scheduling difficulty in a way that allows this case to proceed in April, as AstraZeneca has requested.

Second, as another alternative, the Court indicated at the March 22, 2022 hearing that it has available June 6-10 to try this case, and Dr. Pritchard is available during that window. Mylan is willing to try the case then, and the testimony can proceed according to the burdens. AstraZeneca has now unilaterally withdrawn its preliminary injunction motion (*see* Dkt. No. 528) after putting Mylan to the extraordinary time and expense of responding to it on an emergency basis. That withdrawal was made even though no final decision on the validity of the ’247 patent will be forthcoming for months, even if this case is tried in April. Thus, AstraZeneca’s actions have made unmistakably clear that the urgency it once contended exists is no longer present and the difference between a late-April trial and an early-June one is immaterial. Mylan, of course, would also prefer resolving the claims in this case as soon as possible, but not at the expense of suffering prejudice in their ability to present their case. The burden of a later decision by the Court is preferable to an earlier one that deprives Mylan of the ability to fairly present its case. Accordingly, Mylan alternatively proposes trial for two (or at most three) days the week of June 6. If the Court were to have additional earlier dates become available in the interim, Mylan would of course make every effort to accommodate those dates if the Court prefers them.

Finally, a *de bene esse* deposition prior to the April trial date is impractical here. First, Dr. Pritchard is likely to be Mylan's *only* live trial witness and presenting his direct and cross examination on a pre-recorded basis is prejudicial to Mylan. For example, Mylan would lose the ability to have him consult on responses to the testimony of AstraZeneca's expert. Second, it is unclear how this would technically work. Dr. Pritchard will testify throughout with demonstrative exhibits and both his testimony and exhibits would need to be simultaneously recorded and synchronized. Third, there would be no ability to rule on objections in real time during direct and cross-examination. In depositions that is no difficulty, but for trial testimony by Mylan's key witness on invalidity, it creates the risk that Mylan might lose some testimony (because of a sustained objection) and lack the chance to pursue alternative approaches that would comply with the ruling. For all the reasons, Mylan respectfully requests that the Court proceed with trial according to either of the alternative Mylan has outlined above.

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CERTIFICATE OF SERVICE

I hereby certify that on March 29, 2022, the foregoing document was filed with the Clerk of the Court using the CM/EFC system, which will send notification of such filing to the following counsel of record:

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